



PATENT
Attorney Docket No. STRATA-06948

1634
[Signature]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Allen Comer, *et al.*
Serial No.: 10/087,388
Filed: 03/01/2002
Entitled: Skin Substitutes for Irritancy Testing

Group No.: 1634
Group No: Switzer

AMENDMENT TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: December 13, 2004

By: *Susan M. McClintock*
Susan M. McClintock

Sir or Madam:

Transmitted herewith is an amendment for this application. The fee has been calculated as shown below.

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE	ADDITIONAL FEE
Total Claims	8	—	24	0	×	18.00	\$0.00
Independent Claims	1	—	3	0	×	86.00	\$0.00

· Fee for Request to File a One-Month Extension of Time \$60.00

TOTAL DUE \$60.00

1. A check in the amount of **\$60.00** is attached for filing a one-month extension of time.
2. Petition for extension of time. The undersigned attorney of record hereby petitions for a one-month extension of time pursuant to 37 C.F.R. § 1.136, as may be required, to file this response.

Dated: December 13, 2004

By: *[Signature]*

J. Mitchell Jones
Registration No. 44,174

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
608/218-6900



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Allen Comer *et al.*

Serial No.: 10/087,388

Filed: 03/01/02

Entitled: Skin Substitutes for Irritancy Testing

Group No.: 1634

Examiner: Switzer

DECLARATION OF DR. ALLEN COMER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Date: December 13, 2004

By:


Susan M. McClintock

I, Dr. Allen Comer, state as follows:

1. My present position is Assay Development Manager, Stratatech Corporation.
2. I am an inventor of the above referenced patent application.
3. I have reviewed the Office Action dated August 13, 2004. It is my understanding that the Examiner alleges that the description of two irritant responsive genes is not sufficient to describe an entire genus of irritant responsive genes.
4. At page 40, line 23 to page 41, line 16, the specification teaches that promoters from irritant responsive genes can be used in the reporter gene constructs of the invention as claimed. IL-8 and IL-1 α are provided as exemplary genes from which such promoters can be derived. Example 4 (Pages 55-57) provides detailed teaching of how to construct and screen irritant responsive reporter genes. Thus, methods are provided in the application that one of skill in the

art could use to identify additional irritant responsive reporter genes. Moreover, I note that other irritant responsive genes and promoters were known to those of ordinary skill in the art at the time the priority document was filed (March 2, 2001). These include, but are not limited to the following:

Lisby, S., K. M. Muller, et al. (1995). "Nickel and skin irritants up-regulate tumor necrosis factor-alpha mRNA in keratinocytes by different but potentially synergistic mechanisms."

Int Immunol 7(3): 343-52;

Wakem, P., R. P. Burns, Jr., et al. (2000). "Allergens and irritants transcriptionally upregulate CD80 gene expression in human keratinocytes." J Invest Dermatol 114(6): 1085-92.

5. I further declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 12/13/04



Allen R. Comer
Assay Development Manager

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505 SOUTH ROSA ROAD SUITE 169
MADISON, WI 53719
608.441.2750



Attorney Docket No.:
STRATA-06948

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Allen Comer *et al.*

Serial No.: 10/087,388

Filed: 03/01/02

Entitled: **Skin Substitutes for Irritancy Testing**

Group No.: 1634

Examiner: Switzer

**RESPONSE TO OFFICE ACTION MAILED
MAILED AUGUST 13, 2004**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

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Date: 12/13/04

By: Susan M. McIntock

Dear Sir or Madam:

This communication is responsive to the Office Action mailed August 13, 2004, in the above-mentioned application. The Office Action set a shortened statutory period of three months for Applicants' response. A request for a one-month of extension of time and the appropriate fee is enclosed herewith. If any additional fees are due, Applicants hereby authorize the Commissioner of the Patent and Trademark Office to charge Attorney Deposit Account No. 08-1290 the fee associate with this extension and any other fees associated with this communication. Please reference Attorney Docket No.: STRATA-06948 when charging the Attorney Deposit Account. **Listing of the Claims** begins on page 2 of this paper. **Remarks** begin on page 5 of this paper.